

AMENDED IN SENATE APRIL 12, 2004

SENATE BILL

No. 1765

Introduced by Senator Sher

February 20, 2004

An act to add Chapter 8 (commencing with Section 119400) to Part 15 of Division 104 of the Health and Safety Code, relating to pharmaceutical marketing.

LEGISLATIVE COUNSEL'S DIGEST

SB 1765, as amended, Sher. Pharmaceuticals: marketing practices.

The ~~existing~~ Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of drugs and devices.

This bill would prohibit a pharmaceutical ~~or drug manufacturer company, as defined,~~ from giving gifts to medical or health professionals, with exceptions for drug samples, educational materials, ~~and low-cost items primarily associated with a health care professional's practice, and up to 4 meals per year, valued at \$15 or less, where the drug company representative is present at the meal and information about health products is discussed.~~ The bill would limit the total value of gifts received by a medical or health professional to \$340 in any calendar year.

This bill would require a pharmaceutical company to adopt and update a Comprehensive Compliance Program, that is in accordance with a related federal government publication. The bill would require the Comprehensive Compliance Program to include, among other provisions, policies on interactions with health care professionals and limits on gifts and incentives to medical or health professionals, as imposed by the bill.

This bill would require a pharmaceutical company to annually acknowledge, in writing, compliance with the Comprehensive Compliance Program and the bill, and make its Comprehensive Compliance Program and written acknowledgement of compliance available for public inspection upon request.

This bill would provide that it is not to be construed to create a standard for a pharmaceutical company that is less restrictive than any otherwise applicable provision of existing law.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. *The Legislature finds and declares all of the*
2 *following:*
- 3 (a) *The trade association known as the Pharmaceutical*
4 *Research and Manufacturers of America (PhRMA) has developed*
5 *voluntary guidelines for pharmaceutical companies that pertain to*
6 *gifts and financial incentives provided to doctors.*
- 7 (b) *The Office of Inspector General (OIG) within the United*
8 *States Department of Health and Human Services has developed*
9 *recommendations for pharmaceutical companies that pertain to*
10 *gifts, financial incentives, and other matters relating to the*
11 *development, manufacturing, marketing, and sales of*
12 *pharmaceutical products.*
- 13 (c) *The PhRMA guidelines state, “We are also concerned that*
14 *our interactions with healthcare professionals not be perceived as*
15 *inappropriate by patients or the public at large.”*
- 16 (d) *The OIG guidelines state, “A comprehensive compliance*
17 *program provides a mechanism that addresses the public and*
18 *private sectors’ mutual goals of reducing fraud and abuse;*
19 *enhancing health care provider operational functions; improving*
20 *the quality of health care services; and reducing the cost of health*
21 *care.”*
- 22 (e) *It is therefore the intent of the Legislature in enacting this*
23 *act to achieve the goals expressed in both the PhRMA voluntary*
24 *guidelines and the OIG voluntary guidelines and to ensure greater*
25 *adherence by pharmaceutical companies to both sets of existing*
26 *guidelines by requiring pharmaceutical companies to adopt*
27 *policies that ensure compliance with those guidelines.*



SEC. 2. Chapter 8 (commencing with Section 119400) is added to Part 15 of Division 104 of the Health and Safety Code, to read:

CHAPTER 8. DRUG MARKETING PRACTICES

119400. ~~(a) Pharmaceutical and drug manufacturers~~ *The following definitions shall apply for purposes of this chapter:*

(a) "Dangerous drug" means any drug that is unsafe for self-use and includes either of the following:

(1) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(2) Any drug or device that, pursuant to federal or state law, may be dispensed only by prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code. "Dangerous drug" does not include labeled veterinary drugs.

(b) "Medical or health professional" means any of the following:

(1) A person licensed by state law to prescribe drugs for human patients.

(2) A medical student.

(3) A member of a drug formulary committee.

(c) "Pharmaceutical company" means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Pharmaceutical company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. "Pharmaceutical company" also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state on behalf of a pharmaceutical company. "Pharmaceutical company" does not include a licensed pharmacist.

119402. *(a) Every pharmaceutical company shall adopt a Comprehensive Compliance Program that is in accordance with the April 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers," which was developed by the*

1 *United States Department of Health and Human Services Office of*
2 *Inspector General (OIG). A pharmaceutical company shall make*
3 *conforming changes to its Comprehensive Compliance Program*
4 *within six months of any update or revision to the “Compliance*
5 *Program Guidance for Pharmaceutical Manufacturers.”*

6 *(b) Every pharmaceutical company shall include in its*
7 *Comprehensive Compliance Program policies for compliance*
8 *with the Pharmaceutical Research and Manufacturers of America*
9 *(PhRMA) “Code on Interactions with Health Care*
10 *Professionals,” dated July 1, 2002. The pharmaceutical company*
11 *shall make conforming changes to its Comprehensive Compliance*
12 *Program within six months of any update or revision of the “Code*
13 *on Interactions with Health Care Professionals.”*

14 *(c) Each pharmaceutical company shall include in its*
15 *Comprehensive Compliance Program limits on gifts or incentives*
16 *provided to medical or health professionals, in accordance with*
17 *this chapter.*

18 *(d) The pharmaceutical company shall annually acknowledge,*
19 *in writing, that it is in compliance with both its Comprehensive*
20 *Compliance Program and this chapter. A pharmaceutical*
21 *company shall make its Comprehensive Compliance Program and*
22 *its written acknowledgement of compliance with the program and*
23 *this chapter available for public inspection upon request.*

24 *(e) Nothing in this section shall be construed to create a*
25 *standard for a pharmaceutical company that is less restrictive than*
26 *any otherwise applicable provision of law.*

27 *119404. (a) A pharmaceutical company may not give gifts to*
28 *medical or health professionals, except for the following:*

29 *(1) Professional samples of a drug intended for free*
30 *distribution to patients.*

31 *(2) Educational materials.*

32 *(3) Items primarily associated with a health care professional’s*
33 *practice, including, but not limited to, pens, pads, and tissue boxes,*
34 *as long as the value of each item does not exceed five dollars (\$5).*

35 ~~*(4) Up to four meals per year, valued at no more than fifteen*~~
36 ~~*dollars (\$15) each, where a drug company representative is present*~~
37 ~~*at the meal and information about health products is discussed.*~~

38 *(b) Payments made for legitimate professional services*
39 *provided by a health care or medical professional, including, but*
40 *not limited to, consulting, are not considered gifts for purposes of*

1 this chapter, *provided that the payment does not exceed the fair*
2 *market value of the services rendered.*
3 (c) *The total value of all gifts received by a medical or health*
4 *professional from a pharmaceutical company may not exceed three*
5 *hundred forty dollars (\$340) in any calendar year.*

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